The following corrections or additions to the January 1999 list were made in May 1999.

New Approvals

NADA Number: 141-109

Trade Name:	Avatec®, Baciferm®
Ingredients:	Lasalocid, bacitracin zinc
Sponsor:	Roche Vitamins, Inc.
Approval Date:	04/15/99
Status:	Over-the-counter
Route:	Oral
Species:	Growing turkeys
Drug Form:	Type A Medicated Article to make Type C medicated feed
Concentration:	90.7 g/lb lasalocid Type A Medicated Article, 50 g/lb bacitracin Type A Medicated Article
Indications:	For the prevention of coccidiosis caused by *Eimeria meleagrimitis, E. gallopavonis,* and *E. adenoeides,* and for increased rate of weight gain and improved feed efficiency.
Tolerance:	21 CFR 556.70: Bacitracin: 0.5 ppm negligible residue in uncooked edible tissues of turkeys. Lasalocid: An acceptable daily intake of 0.01 mg/kg/day is established.
Withdrawal:	Zero days

21CFR 558.78 and 558.311

Supplemental Approvals

NADA Number: 138-935

Trade Name:	Pennchlor Type A Medicated Article
Ingredients:	Chlortetracycline hydrochloride
Sponsor:	PennField Oil Co.
Approval Date:	03/24/99
Status:	Over-the-counter
Route:	Oral
Species:	Chickens (not laying eggs for human consumption), turkeys, cattle, swine, and sheep
Drug Form:	Type A Medicated Article to make Type B and C medicated feeds
Concentration:	50, 60, 70, 80, and 90 g/lb
Indications:	**Chickens**: For increased rate of weight gain and improved feed efficiency. For the control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline; chronic respiratory disease and air sac infection caused by *Mycoplasma gallisepticum* and *Escherichia coli* susceptible to chlortetracycline. Also for the reduction of mortality due to *Escherichia coli* infections susceptible to chlortetracycline. **Turkeys**: For increased rate of weight gain and improved feed efficiency. For the control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis), infectious synovitis caused by *Mycoplasma synoviae,* and chronic respiratory disease and air sac infection caused by *Mycoplasma gallisepticum* and *Escherichia coli* susceptible to chlortetracycline. For the control of hexamitiasis caused by *Hexamita meleagridis* susceptible to chlortetracycline. Also for the reduction of mortality due to *Escherichia coli* infections susceptible to chlortetracycline. In turkey poults not over 4 weeks of age: for the reduction of mortality due to paratyphoid caused by *Salmonella typhimurium* susceptible to chlortetracycline. **Swine**: For an increased rate of weight gain and improved feed efficiency. For reducing the incidence of cervical lymphadenitis (jowl abscesses) caused by group *E. streptococci* susceptible to chlortetracycline. In breeding swine for the control of leptospirosis (reducing the instances of abortion and shedding of leptospirae) caused by *Leptospira pomona* susceptible to chlortetracycline. For the treatment of bacterial enteritis caused *by Escherichia coli* and *Salmonella cholerasuis* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline.

NADA Number: 138-935, con't

Sheep: For an increased rate of weight gain and improved feed efficiency. Also for reducing the incidence of (vibrionic) abortion caused by *Campylobacter fetus* infection susceptible to chlortetracycline.
Calves, beef cattle, and non-lactating dairy cattle: For an increased rate of weight gain and improved feed efficiency. Also for the treatment and control of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia (shipping fever complex) caused by *Pasteurella multocida*; for control of active infection of anaplasmosis caused by *Anaplasma marginale*.

Tolerance: 21CFR 556.150: Chlortetracycline: The tolerances for edible tissues are as follows: 6 ppm in liver, 2 ppm in muscle, 12 ppm in kidney, and 12 ppm in fat.

Withdrawal: 1 day

This supplemental application provides for a revised withdrawal period of 1-day following feeding of Type B and C medicated feeds to cattle.

21CFR 558.128

ANADA Number: 200-008

Trade Name: Oxy-Tet™ 200, Bio-Mycin® 200
Ingredients: Oxytetracycline
Sponsor: Boehringer Ingelheim Vetmedica, Inc.
Approval Date: 03/16/99
Status: Over-the-counter
Route: Intramuscular, subcutaneous, intravenous in cattle; intramuscular in swine
Species: Beef cattle, non-lactating dairy cattle, and swine
Drug Form: Liquid (solution)
Concentration: 200 mg/mL
Indications: **Cattle**: For the treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Haemophilus* spp.; infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*; foot rot and diphtheria caused by *Fusobacterium necrophorum*; bacterial enteritis (scours) caused by *Escherichia coli*; wooden tongue caused by *Actinobacillus lignieresii*; leptospirosis caused by *Leptospira pomona*; and wound infections and acute metritis caused by strains of staphylococci and streptococci organisms sensitive to oxytetracycline.
Swine: For the treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli*; pneumonia caused by *Pasteurella multocida*; and leptospirosis caused by *Leptospira pomona*. In sows, as an aid in the control of infectious enteritis caused by *Escherichia coli* (baby pig scours, colibacillosis) in suckling pigs.
Tolerance: 21CFR 556.500: Tolerances are established for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline, in tissues of cattle, beef calves, non-lactating dairy cattle, dairy calves, swine, sheep, chickens, turkeys, catfish, lobsters, and salmonids, as follows: 2 parts per million (ppm) in muscle, 6 ppm in liver, and 12 ppm in fat and kidney.
Withdrawal: 28 days

This supplemental application establishes a 28 day withdrawal period for subcutaneous use in cattle and intramuscular use in swine (all approved routes of administration in cattle and swine).

21CFR 522.1660

NADA Number: 128-409

Trade Name:	Ivomec® Injection for Cattle and Swine
Ingredients:	Ivermectin
Sponsor:	Merial Limited
Approval Date:	04/01/99
Status:	Over-the-counter
Route:	Subcutaneous
Species:	Cattle, swine, reindeer, American bison, and ranch raised fox
Drug Form:	Liquid (solution)
Concentration:	1% (10 mg/mL)
Indications:	**Cattle**: For the treatment and control of various species of gastrointestinal roundworms, lungworms, grubs, biting and sucking lice, and mange mites. Gastrointestinal roundworms (adults and 4th stage larvae): *Ostertagia ostertagi* (including inhibited larvae), *O. lyrata, Haemonchus placei, Trichostrongylus axei, T. colubriformis, Cooperia oncophora, C. punctata, C. pectinata, Oesophagostomum radiatum, Bunostomum phlebotomum, Nematodirus helvetianus* (adults only), *N. spathiger* (adults only). Lungworms (adults and 4th stage larvae): *Dictyocaulus viviparus*. Grubs (parasitic stages): *Hypoderma bovis, H. lineatum*. Sucking Lice: *Linognathus vituli, Haematopinus eurysternus, Solenopotes capillatus*. Mites (Scabies): *Psoroptes ovis* (Syn. *P. communis* var. bovis), *Sarcoptes scabiei* var. bovis. Persistent activity: Ivomec Injection has been proved to effectively control infections and to protect cattle from re-infection with *Dictyocaulus viviparus* for 28 days and *Ostertagia ostertagi* for 21 days after treatment; *Oesophagostomum radiatum, Haemonchus placei, Trichostrongylus axei, Cooperia punctata*, and *Cooperia oncophora* for 14 days after treatment. **Swine**: For the treatment and control of the following species of gastrointestinal roundworms, lungworms, lice, and mange mites Gastrointestinal roundworms: Large roundworms, *Ascaris suum* (adults and 4th stage larvae); red stomach worm, *Hyostrongylus rubidus* (adults and 4th stage larvae); nodular worm, *Oesophagostomum* spp. (adults and 4th stage larvae); threadworm, *Strongyloides ransomi* (adults only) Somatic Roundworm Larvae: Threadworm, *Strongyloides ransomi* (somatic larvae) Lungworms: *Metastrongylus* spp. (adults only) Lice: *Haematopinus suis* Mites: *Sarcoptes scabiei* var. *suis* **Reindeer**: For the treatment and control of warbles (*Oedemagena tarandi*) **American Bison**: For the treatment and control of grubs (*Hypoderma bovis*) **Ranch raised fox**: For treatment and control of ear mites (Otodectes cynotis)
Tolerance:	21CFR 556.344: The ADI for total residues of ivermectin is 1 microgram per kilogram of body weight per day. Liver. A tolerance is established for 22,23-dihydroavermectin B1a (marker residue) in liver (target tissue) as follows: Cattle 100 parts per billion, Swine 20 parts per billion, Sheep 30 parts per billion, Reindeer 15 parts per billion, American bison 15 parts per billion. Muscle residues are not indicative of the safety of other edible tissues. A tolerance is established for 22,23-dihydroavermectin B1a (marker residue) in muscle as follows: swine 20 parts per billion; cattle 10 parts per billion.
Withdrawal:	35 days
Exclusivity:	3 years

This supplemental application extends the period of persistent effect against infections of *Dictyocaulus viviparus* from 21 days to 28 days after treatment, and establishes an ADI in cattle muscle for total residues of ivermectin.

21CFR 522.1192 and 556.344

NADA Number: 140-833

Trade Name:	Ivomec® Plus Injection for Cattle
Ingredients:	Ivermectin, clorsulon
Sponsor:	Merial Limited
Approval Date:	04/01/99
Status:	Over-the-counter
Route:	Subcutaneous
Species:	Beef cattle and dairy cattle under 20 months old
Drug Form:	Liquid (solution)
Concentration:	Ivermectin 1% (10 mg/mL), clorsulon 10% (100 mg/mL)
Indications:	For the treatment and control of various species of gastrointestinal roundworms, lungworms, liver flukes, grubs, biting and sucking lice, and mange mites in cattle. Gastrointestinal roundworms (adults and 4th stage larvae): *Ostertagia ostertagi* (including inhibited larvae), *O. lyrata, Haemonchus placei, Trichostrongylus axei, T. colubriformis, Cooperia oncophora, C. punctata, C. pectinata, Oesophagostomum radiatum, Bunostomum phlebotomum, Nematodirus helvetianus* (adults only), *N. spathiger* (adults only) Lungworms (adults and 4th stage larvae): *Dictyocaulus viviparus* Grubs (parasitic stages): *Hypoderma bovis, H. lineatum* Sucking Lice: *Linognathus vituli, Haematopinus eurysternus, Solenopotes capillatus* Mites (Scabies): *Psoroptes ovis* (Syn. *P. communis* var. bovis), *Sarcoptes scabiei* var. *bovis* Liver flukes (adults only): Fasciola hepatica Persistent activity: Ivomec has been proved to effectively control infections and to protect cattle from re-infection with *Dictyocaulus viviparus* for 28 days and *Ostertagia ostertagi* for 21 days after treatment; *Oesophagostomum radiatum, Haemonchus placei, Trichostrongylus axei, Cooperia punctata*, and *Cooperia oncophora* for 14 days after treatment.
Tolerance:	21CFR 556.344: The ADI for total residues of ivermectin is 1 microgram per kilogram of body weight per day. Liver. A tolerance is established for 22,23-dihydroavermectin B1a (marker residue) in liver (target tissue) as follows: cattle 100 parts per billion. Muscle residues are not indicative of the safety of other edible tissues. A tolerance is established for 22,23-dihydroavermectin B1a (marker residue) in muscle as follows: cattle 10 parts per billion.
Withdrawal:	49 days
Exclusivity:	3 years

This supplemental application extends the period of persistent effect against infections of *Dictyocaulus viviparus* from 21 days to 28 days.

21CFR 522.1193 and 556.344

NADA Number: 040-209

Trade Name:	Rofenaid® 40 Type A Medicated Article
Ingredients:	Sulfadimethoxine, ormetoprim
Sponsor:	Roche Vitamins, Inc.
Approval Date:	04/01/99
Status:	Over-the-counter
Route:	Oral
Species:	Chukar partridge, chickens, and turkeys
Drug Form:	Type A Medicated Article to make Type C medicated feeds
Concentration:	113.5 g sulfadimethoxine and 68.1 g ormetoprim/lb
Indications:	**Chukar partridges**: For the prevention of coccidiosis caused by *Eimeria kofoidi* and *E. legionensis* . **Chickens**: As an aid in the prevention of coccidiosis caused by all *Eimeria* species known to be pathogenic to chickens, namely *E. tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati* and *E. maxima*, and bacterial infections due to *Haemophilus galmaximum* and *H. gallinarum* (infectious coryza), E. *coli* (colibacillosis) and *Pasteurella multocida* (fowl cholera). **Turkeys**: As an aid in the prevention of coccidiosis caused by all *Eimeria* species known to be pathogenic to turkeys, namely, *E. adenoeides, E. gallopavonis*, and *E. meleagrimitis* and bacterial infection due to *Pasteurella multocida* (fowl cholera).
Tolerance:	21 CFR 556.640: Sulfadimethoxine: A tolerance of 0.1 part per million (ppm) is established for negligible residues in uncooked edible tissues of chickens, turkeys, cattle, ducks, salmonids, catfish and chukar partridges. 21 CFR 556.490: Ormetoprim: A tolerance of 0.1 part per million (ppm) is established for negligible residues in uncooked edible tissues of chickens, turkeys, ducks, salmonids, catfish, and chukar partridges.
Withdrawal:	Chickens: 5 days; turkeys: 5 days

This supplemental application provides for the addition of a new species (chukar partridges).

21CFR 556.490, 556.640, and 558.575

Actions Taken by FDA Center for Veterinary Medicine

NADA Number: 131-675

Trade Name:	Safe-Guard® Dewormer 20%
Ingredients:	Fenbendazole
Sponsor:	Hoechst Roussel Vet
Approval Date:	04/16/99
Status:	Over-the-counter
Route:	Oral
Species:	Swine, zoo animals, and wildlife animals
Drug Form:	Type A Medicated Article to make Type C medicated feeds
Concentration:	20% (90.7 g/lb)
Indications:	**Swine**: For use in feed for the removal of adult stage lungworms (*Metastrongylus apri* and *M. pudendotectus*); adult and larvae ($L_{3, 4}$ stages – liver, lung, intestinal forms) large roundworms (*Ascaris suum*); adult stage nodular worms (*Oesophagostomum dentatum*, *O. quadrispinulatum*); small stomach worms (*Hyostrongylus rubidus*); adult and larvae ($L_{2, 3, 4}$) stages of intestinal mucosal forms whipworms (*Trichuris suis*); adult and larvae kidney worms (*Stephanurus dentatus*). **Zoo and wildlife animals**: For removal and control of internal parasites in hoofed zoo and wildlife animals as follows: **Feral swine** (*Sus scrofa*) For the treatment of kidney worm (*Stephanurus dentatus*), roundworm (*Ascaris suum*), nodular worm (*Oesophagostomum dentatum*). **Ruminants** (subfamily Antilopinae, Hippotraginae, Caprinae) For the treatment for small stomach worm (*Trichostrongylus* spp.), thread necked intestinal worm (*Nematodirus* spp.), barberpole worm (*Haemonchus* spp.), whipworm (*Trichuris* spp.) **Rocky mountain bighorn sheep** (*Ovis canadensis canadensis*): For the treatment and control of *Protostrongylus* spp.
Tolerance:	Not needed for swine
Withdrawal:	Swine: zero days; wildlife: 14 days before hunting season

This supplemental application provides for an increase in the concentration in Type C medicated feed from 10-80 g/ton to 10-300 g/ton to allow for restricted feeding of sows.

21CFR 558.258

Suitability Petition Action

Number:	99P-0627/CP1
Sponsor:	Phoenix Scientific, Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug clorsulon which differs from the pioneer product, ivermectin/clorsulon (Ivomec® F Injection for Cattle), Merial Ltd., NADA 140-833, by the following characteristic: Clorsulon generic is a is a single ingredient product whereas the pioneer product is a combination product.
Action:	Denied on 05/27/99

Final Rule

The final rule published in the Federal Register of May 24, 1999 states that specifications for ingredients other than the active ingredient(s) are not needed.